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# Structural Integrity of Balloon-Expandable Stents After Transcatheter Aortic Valve Replacement

## Assessment by Multidetector Computed Tomography

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**Objectives** This study sought to evaluate the structural integrity of balloon-expandable stents used in transcatheter aortic valve replacement.

**Background** Underexpansion, deformation, or fracture of stent frames may affect transcatheter heart valve (THV) function and durability.

**Methods** Patients >1 year after transcatheter aortic valve replacement underwent multidetector computed tomography. Geometry of the stent frame was assessed for circularity; eccentricity; minimum and maximum external diameter; and expansion at the inflow, mid-stent, and outflow levels, as well as for stent fracture. THV noncircularity was defined as stent eccentricity >10% (1 – minimum diameter/maximum diameter) and THV underexpansion when expansion <90% (multidetector computed tomography derived external valve area/nominal external valve area). Echocardiography was performed after implantation and annually.

**Results** Fifty patients underwent multidetector computed tomography at an average of 2.5 ± 0.9 years after transcatheter aortic valve replacement (35 Sapien, 8 Sapien XT, and 7 Cribier-Edwards valves [all Edwards Lifesciences, Irvine, California). The mean external diameter for the 23- and 26-mm valves was 23.3 ± 0.9 mm and 25.9 ± 0.9 mm, respectively. Circularity was present in 96% (48 of 50) and median eccentricity was 2.0% (interquartile range: 1.2% to 3.0%). Mean THV expansion was 104.1 ± 7.4%, which increased from stent inflow to outflow (100.8 ± 7.6% vs. 108.1 ± 6.9%, $p < 0.001$). Stent fracture was not observed. Underexpanded valves (8% [4 of 50]) and noncircular valves (4% [2 of 50]) demonstrated stable hemodynamic function on annual echocardiography.

**Conclusions** Balloon-expandable aortic valves have excellent rates of circularity with low eccentricity and maintain full expansion without stent fracture at an average 2.5 years after implantation. (J Am Coll Cardiol Intv 2012;5:525–32) © 2012 by the American College of Cardiology Foundation

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Failure of surgically implanted bioprosthetic valves most commonly occurs late and results from leaflet degeneration associated with calcification, leaflet tears, or pannus (1,2). Transcatheter heart valves (THV) have proven short- and mid-term durability (3–5). Nevertheless, it is anticipated that THV will also suffer from late leaflet degeneration. Whether this will occur earlier or later in THV is, as yet, unknown.

A unique concern with respect to THV relates to the design characteristics of the stent frame. The requirement that this be low profile, compressible, and expandable necessitates potential compromises in terms of structural strength and durability. Complete and symmetrical expansion of the stent frame is critical for secure fixation, paravalvular sealing, maximizing orifice area, and both leaflet coaptation and durability. Incomplete or asymmetrical expansion, late recoil, or strut fracture may lead to instability, migration, stenosis, regurgitation, or leaflet degeneration (6–8). Evidence of mid-to-late structural integrity and durability of THV stents is limited. The significance of gross deformity of the valve frame on valve hemodynamics and premature valve failure has not been described. We used multidetector computed tomography (MDCT) to assess balloon-expandable THV for expansion, eccentricity, and stent fracture.

**Abbreviations and Acronyms**

CT = computed tomography

MDCT = multidetector computed tomography

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve(s)

## Methods

**Subject selection.** Transcatheter aortic valve replacement (TAVR) was performed with the Cribier-Edwards valve, Sapien valve, or Sapien XT valve (all Edwards Lifesciences, Irvine, California) in 316 patients between January 2005 and June 2010 at St. Paul's Hospital, Vancouver, British Columbia. Fifty patients alive >1 year after implantation and without renal impairment (glomerular filtration rate <35 ml/min) underwent MDCT between January 2010 and June 2011. The study was conducted with local Institutional Review Board approval with informed consent. Patients underwent echocardiography assessment of THV function before hospital discharge after TAVR and annually. Prosthetic aortic regurgitation was assessed by transthoracic echocardiography performed after implantation and then annually and classified as either transvalvular or paravalvular (9).

**MDCT image acquisition and analysis.** MDCT examinations were performed on 2 64-slice scanners, a VCT XT and a Discovery HD 750 (both GE Healthcare, Milwaukee, Wisconsin). We injected 80 to 120 ml of iodixanol 320 (GE Healthcare, Princeton, New Jersey) at 5 ml/s followed by 30 ml of normal saline. MDCT scanner detector collimation width was 0.625 mm, detector coverage was 40 mm, reconstructed slice thickness was 1.25 mm, and the slice interval was 1.25 mm. Gantry rotation time was 0.35 s, and the scan pitch ranged between 0.16 and 0.20 (adjusted per heart rate). Electrocardiogram-gated dose modulation was used for all cases with a peak tube current (300 to 725 mA) and tube voltage (100 to 120 kVp) set based on body mass index. Computed tomography (CT) images were reconstructed using both standard and hard convolution kernels to obviate the blooming and beam hardening effect of the valve stent. The effective radiation dose was

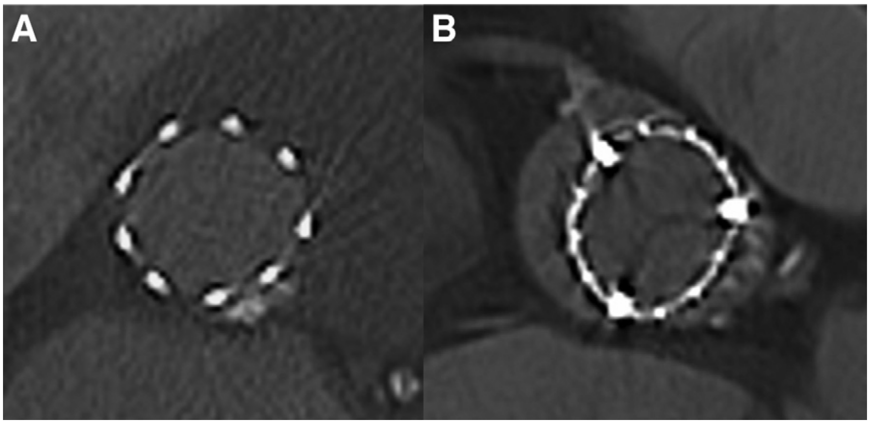


**Figure 1. THV Eccentricity as Assessed by MDCT**

**(A)** Circular 23-mm Sapien XT valve (minimum external stent diameter = 23.2 mm, maximum external stent diameter = 23.3 mm, eccentricity 0.4%) (Edwards Lifesciences, Irvine, California). **(B)** Noncircular 23-mm Sapien valve (minimum external stent diameter = 22.0 mm, maximum external stent diameter = 25.2 mm, eccentricity 12.7%) (Edwards Lifesciences). MDCT = multidetector computed tomography; THV = transcatheter heart valve.

estimated by multiplying the dose-length product with an established conversion factor of 0.014 mSv/(mGy·cm) as has been proposed by the European Working Group for Guidelines on Quality Criteria in CT (10).

Each THV was assessed by MDCT at 3 cross-sectional levels—inflow, mid-stent, and outflow—following the reformatting of aortic root in short axis (11). At each level, the minimum external diameter, maximum external diameter, and external valve area were measured. THV area was measured by tracing along the external margins of the THV frame. All stent levels were measured 3 times by an experienced level 3 coronary CT angiography reader with the data shown representing the mean of the 3 measurements. Measurements were taken in diastole at 75% of the R-R interval owing to optimal image quality and a lack of difference in stent size and configuration across the cardiac cycle owing to the rigid stent structure.

**THV ECCENTRICITY/CIRCULARITY.** THV eccentricity was calculated as: 1 − minimum external stent diameter/maximum external stent diameter. Circular THV were defined as having an eccentricity of <10% (interquartile range: 12% to 14%) (Fig. 1). Given the low rates (2 of 50) of THV eccentricity, >10% in our study cohort, and the unknown impact of THV eccentricity on valve function, the hemodynamics of THV with moderate or severe eccentricity (>5%) was compared with those with trivial or mild eccentricity (<5%).

**THV EXPANSION.** THV expansion was defined as the MDCT-derived external valve area divided by the nominal external valve area (Fig. 2) (12). Nominal external valve area is 4.15 and 5.31 cm$^2$ for the 23- and 26-mm valves, respectively. An underexpanded valve was defined as having an expansion ratio of ≤90%. The impact of underexpansion on valve hemodynamic function with serial echocardiography was assessed.

**THV OVERSIZING.** The numerical difference between the implanted valve size and transesophageal echocardiography annulus diameter was used to classify THV as being mildly oversized (THV 0 to 2 mm greater than the transesophageal echocardiography annulus diameter) or moderately oversized (THV 3 to 5 mm greater than the transesophageal echocardiography annulus diameter). The impact of echo-

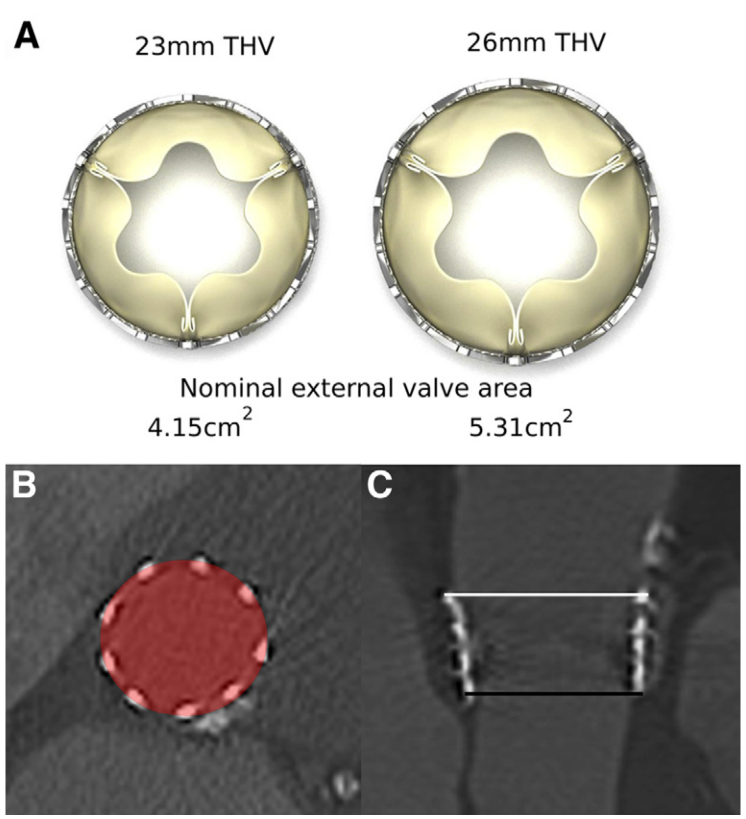


**Figure 2. THV Expansion as Assessed by MDCT**

**(A)** Nominal external valve area of the 23- and 26-mm balloon-expandable valves. **(B)** THV expansion is calculated by dividing MDCT-derived external valve area by nominal external valve area. **(C)** A Sapien 26-mm valve (Edwards Lifesciences, Irvine, California) underexpanded at the inflow with increasing expansion toward the outflow level (inflow external valve area = 460 mm$^2$, inflow expansion = 86.5%, outflow external valve area = 597 mm$^2$, outflow expansion: 112.4%). Abbreviations as in Figure 1.

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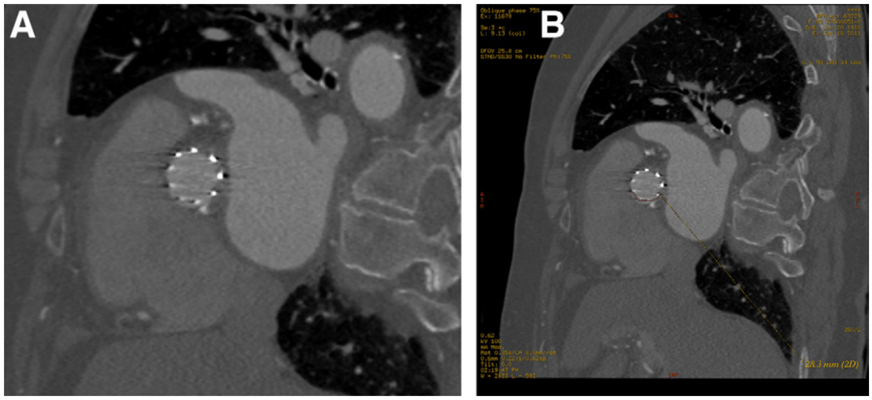


**Figure 3. Double Oblique Transverse Images of a 93-Year-Old Woman 2.2 Years After TAVR**

**(A)** The subject presents with nonapposition of approximately 35%. The THV is nonapposed from the 4- to 7-o'clock position over approximately 28 mm **(B)** in length or 35% of the 80-mm perimeter of the valve. TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

cardiographic oversizing on expansion and eccentricity was analyzed.

**THV POSITION AND MALAPPOSITION.** THV depth was measured as the distance from the inflow of the valve to the sinus of Valsalva floor. The outflow level of the valve was classified as either above or below the inferior border of the left main ostium. THV malapposition with the aortic annulus was assessed visually and quantitatively by MDCT. The stent nonapposed component of the THV was measured using a curved measurement tool, and then divided by the measured perimeter of the THV to calculate a percentage of malapposition (Figs. 3A and 3B).

**Statistical analysis.** Continuous variables are described as mean ± SD or medians with interquartile range. Categorical variables are described by frequencies and percentages. Continuous parametric variables were compared using unpaired and paired Student *t* test. Continuous nonparametric variables were compared using the Mann-Whitney *U* test. Categorical variables were compared using Fisher exact test. One-way analysis of variance was used to compare the difference in means among 3 groups. A p value $<0.05$ was considered statistically significant. Analyses were performed using SPSS statistics software (version 19.0, SPSS, Inc., Chicago, Illinois).

## Results

Fifty patients underwent MDCT assessment at an average 2.5 ± 0.9 years after TAVR (range 1 to 4 years). Clinical characteristics are described in Table 1. The mean effective dose of the electrocardiographic-gated cardiac CT examinations was 7.8 ± 1.2 mSv. Of the 50 THV, 35 (70%) were Sapien, 8 (16%) Sapien XT, and 7 (14%) Cribier-Edwards valves. The mean external diameter across all stent levels for the 23- and 26-mm valves was 23.3 ± 0.9 mm and 25.9 ± 0.9 mm, respectively. THV circularity was present in 96% (48 of 50) and 98% (144 of 147) of analyzed stent levels were circular (3 segments noninterpretable). Median THV eccentricity was 2.0% (interquartile range: 1.2% to 3.0%) (Table 2). There was no difference in eccentricity from THV inflow to outflow (Table 2) or between THV types (Table 3). Patients with moderate THV eccentricity (7 of 50) had greater transaortic mean gradients before TAVR than did those with a mild THV eccentricity (53.1 ± 16.4 mm Hg vs. 41.5 ± 15 mm Hg, p = 0.047). The post-

**Table 1. Clinical Characteristics (n = 50)**

| | |
|---|---|
| Male/female, n | 24/26 |
| Age, yrs | 81.1 ± 7.5 |
| BMI, kg/m$^2$ | 25.8 ± 4.8 |
| LVEF, % | 55.1 ± 13.2 |
| STS PROM | 8.5 ± 4.0 |
| Diabetes | 5.0 (10/50) |
| GFR, ml/min | 68.5 ± 20.4 |
| Prior CABG | 44 (22/50) |
| Baseline valve area, cm$^2$ | 0.62 ± 0.17 |
| Baseline gradient, mm Hg | 42.9 ± 15.8 |
| Valve size, 23 mm/26 mm | 14/36 |
| Valve type, n | 7 CE, 35 SAP, 8 XT |
| Valve redilated | 10 (5/50) |
| Final valve area, cm$^2$ | 1.52 ± 0.41 |
| Final gradient, mm Hg | 10.9 ± 4.6 |
| Pacemaker post-implantation* | 4.6 (2/44) |
| Moderate/severe PAR post-implantation | 2 (1/50) |

Values are n, % (n/N), or mean ± SD. Sapien, Sapien XT, and Cribier-Edwards valves are products of Edwards Lifesciences (Irvine, California). *6 patients had a pacemaker before TAVR.

BMI = body mass index; CABG = coronary artery bypass graft; CE = Cribier-Edwards valve; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; PAR = paravalvular aortic regurgitation; SAP = Sapien valve; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; TAVR = transcatheter aortic valve replacement; XT = Sapien XT valve.

**Table 2. THV Eccentricity and Expansion at an Average 2.5 Years After Implantation**

| | | THV Level | | | |
|---|---|---|---|---|---|
| | Overall | Inflow | Mid-Stent | Outflow | p Value* |
| Eccentricity, % | 2.0 (1.2–3.0) | 2.1 (1.2–3.4) | 1.9 (0.9–2.9) | 1.9 (1.1–2.8) | 0.60 |
| Expansion, % | 104.1 ± 7.4 | 100.8 ± 7.6 | 103.5 ± 5.6 | 108.4 ± 7.1 | <0.01 |
| 23-mm THV diameter | 23.2 ± 0.7 | 22.9 ± 0.7 | 23.2 ± 0.5 | 23.4 ± 0.8 | 0.01 |
| 26-mm THV diameter | 25.9 ± 0.9 | 25.5 ± 1.0 | 25.9 ± 0.6 | 26.2 ± 0.9 | <0.01 |

Values are median (25th to 75th interquartile range) or mean ± SD. *The p value compares inflow to outflow levels.
THV = transcatheter heart valve.

TAVR gradient and aortic valve area at discharge and at 1 year did not differ among these groups (Table 4).

Mean THV expansion was 104.1 ± 7.4% with a significant increase from the inflow to outflow THV level (100.8 ± 7.6% vs. 108.1 ± 6.9%, $p < 0.001$) (Table 2). There was no difference in expansion among THV type (Table 3). THV were fully expanded in 92% (46 of 50) and in 97.3% (143 of 147) of analyzed stent levels. Underexpansion occurred at the inflow level only (Table 5). Valve geometry and hemodynamics out to 3 years for the underexpanded valves and noncircular valves is detailed in Table 5. There was no difference in eccentricity or expansion between mildly oversized THV compared with moderately oversized THV (Table 6). There were no cases of stent fracture identified by MDCT. None of the 5 THV that were redilated was noncircular or underexpanded.

The outflow portion of the THV was located below the inferior border of the left main ostium in 52% (26 of 50) of cases. The mean depth of implant was 1.1 ± 3.1 mm. A permanent pacemaker was implanted for complete heart block after TAVR in 1 case where the THV depth was 6.5 mm (a second pacemaker was implanted early after TAVR in the setting of slow atrial fibrillation where the implant depth was 3.0 mm). THV malapposition at the annular level was present in 26% (13 of 50), where the mean percentage of stent being malapposed was 27.0 ± 13.8%. In those with stent malapposition, at least mild paravalvular aortic regurgitation was present in 53.8% (7 of 13) compared with 35.1% (13 of 37) of THV with complete annular apposition ($p = 0.33$).

## Discussion

The clinical importance of THV eccentricity or underexpansion is unknown; however, there is indirect evidence to suggest that valve distortion may lead to accelerated calcification and fibrosis in an animal model (8,13). Our study demonstrates that balloon-expandable valves have excellent rates of circularity with low eccentricity and maintain full expansion without stent fracture late after implantation within this selected population.

**THV eccentricity and circularity.** Noncircular THV expansion has been defined as an eccentricity of >10% (12,14,15). To surpass this threshold, the difference between the short- and long-axis diameters needs to be quite marked (approximately 2.3 and 2.6 mm for the 23- and 26-mm valves, respectively). We have demonstrated that eccentricity of balloon-expandable valves late after implantation is low with an average 2% difference between the short and long external valve diameters within this selected population. This corresponds to an average absolute difference in the short and long diameters of 0.46 and 0.52 mm for the 23- and 26-mm THV, respectively. Interestingly, THV eccentricity did not differ for measurements taken at the annular inflow level versus the outflow level, suggesting annular eccentricity may not significantly affect THV eccentricity. This finding may be a result of undersizing of the prosthesis relative to the aortic annulus using the current transesophageal echocardiography sizing guidelines. It may also represent a certain level of compliance of the aortic annulus as it has been well established with MDCT that the aortic

**Table 3. Eccentricity and Expansion Based on THV Type**

| | Valve Type | | | |
|---|---|---|---|---|
| | Sapien XT | Sapien | Cribier-Edwards | p Value |
| Analyzed segments | 23 | 103 | 21 | |
| Expansion, % | 103.5 ± 8.0 | 104.8 ± 7.2 | 101.6 ± 7.2 | 0.13 |
| Eccentricity, % | 1.7 (0.6–3.8) | 2.1 (1.2–3.2) | 2.1 (0.9–2.7) | 0.21 |

Values are n, mean ± SD or median (25th to 75th interquartile range). Sapien, Sapien XT, and Cribier-Edwards valves are products of Edwards Lifesciences (Irvine, California).
THV = transcatheter heart valve.

**Table 4. The Impact of Moderate-to-Severe THV Eccentricity on Hemodynamic Function**

| | | Before TAVR | | <7 Days After TAVR | | 1 Year After TAVR | |
|---|---|---|---|---|---|---|---|
| Eccentricity | n | MG | AVA | MG | AVA | MG | AVA |
| <5% | 43 | 41.5 ± 15.0 | 0.62 ± 0.17 | 10.6 ± 4.4 | 1.51 ± 0.45 | 10.8 ± 3.7 | 1.46 ± 0.26 |
| >5% | 7 | 53.1 ± 16.4 | 0.62 ± 0.20 | 11.6 ± 6.6 | 1.60 ± 0.13 | 12.8 ± 3.8 | 1.45 ± 0.19 |
| p Value | | 0.05 | 0.92 | 0.57 | 0.62 | 0.18 | 0.95 |

Values are mean ± SD.
AVA = aortic valve area; MG = mean aortic gradient; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

annulus most commonly has an elliptical configuration before TAVR (12).

The etiology of stent eccentricity appears most likely to be a result of annular/valvular calcification and eccentricity of the aortic annulus. A high degree of THV eccentricity may be associated with increased paravalvular aortic regurgitation (14). Theoretically, marked THV eccentricity may also be associated with premature valve degeneration because of altered leaflet coaptation, strain, or shear forces. These concerns may be of greater importance in patients with markedly eccentric annuli, such as in the setting of bicuspid aortic valves (6,7). What level of THV eccentricity is required to have an impact on long-term durability remains unknown.

**Noncircular THV.** There were only 2 noncircular THV in our series. In both cases, serial post-implantation echocardiography demonstrated good and stable valve function over the follow-up period (up to 3 years in 1 case). However, mild paravalvular regurgitation was present in both cases. This may represent an incomplete annular seal secondary to annular calcification that may also have contributed to the THV eccentricity. THV with at least moderate eccentricity (>5%) had higher mean aortic gradients at baseline than did THV with mild eccentricity; however, there was no difference in baseline aortic valve area. It is possible that increasing severity of aortic stenosis is associated with increasing THV eccentricity owing to a greater degree of valve calcification and leaflet restriction. There was no difference in the post-implantation gradients out to 1 year for THV with moderate eccentricity compared with mild eccentricity.

**THV expansion.** The clinical importance of failing to achieve nominal THV expansion is currently unclear; however, it may be hypothesized that a grossly underexpanded THV could affect long-term valve durability. Underexpansion may be due to prosthesis oversizing relative to the annular size, THV stent recoil, or inadequate THV balloon expansion (small or underfilled balloon or short duration of balloon expansion). This study demonstrates that complete THV expansion was seen in almost all cases regardless of THV type. Despite this, there were small differences in expansion between THV levels, with expansion being less at the inflow compared with at the outflow level. This may represent restriction by the aortic annulus, resistance to expansion by the fabric cuff covering the THV inflow, or overexpansion of the uncovered outflow portion of the THV.

Recoil of the THV stent could not be directly assessed due to the absence of matched early and late post-implantation MDCT scans. However, given the high rates of complete late THV expansion, it would appear unlikely that stent recoil is a problem with these balloon-expandable valves.

**Underexpanded THV.** There were 4 cases of THV underexpansion. Underexpansion was limited to the inflow level, with valves becoming fully expanded at the mid-stent and outflow levels. One underexpanded THV had possible prosthetic aortic valve stenosis as defined by the Valvular Academic Research Consortium (9). This was present on echocardiography immediately after implantation and persisted without deterioration during 3-year follow-up. These hemodynamics are unlikely to be due to patient prosthesis mismatch as a 26-mm valve was implanted in a 22-mm annulus on transesophageal echocardiogram.

**Stent fracture.** Stent fracture as assessed on MDCT was absent in all cases. Stent fracture may lead to deformity of the stent, tearing of the leaflet or sewing fabric, and premature valve degeneration. However, it is possible that a fracture in the absence of deformity was missed by MDCT. It has been suggested that fluoroscopy may offer a more accurate assessment of nondisplaced fractures for the self-expandable transcatheter heart valve made of nitinol with thin stent struts (16). Although data are limited, the thicker struts of the balloon-expandable stent frame are likely more amenable to assessment with MDCT, and MDCT has sufficient resolution to reliably detect the more relevant displaced fractures.

**Comparison with other post-TAVR CT studies.** This study is the first to describe geometry of balloon-expandable valves late after implantation. Geometry early after implantation of balloon-expandable valves has been described in 1 other study (14). Delgado et al. (14) analyzed 42 consecutive patients within 1 week of implantation with a Sapien valve. Circularity was present in 84% (36 of 42); however, 2 patients had bicuspid aortic stenosis. They demonstrated that patients with moderate paravalvular aortic regurgitation

**Table 5. Noncircular and Underexpanded THV**

| | Noncircular Valves | | Underexpanded Valves | | | |
|---|---|---|---|---|---|---|
| | Case 1 | Case 2 | Case 1 | Case 2 | Case 3 | Case 4 |
| Valve | | | | | | |
| Type | Sapien XT | Sapien | Sapien | Sapien | Sapien | CE |
| Size | 26 | 23 | 26 | 26 | 26 | 26 |
| TEE annulus, mm | 23 | 21 | 23 | 24 | 23 | 22 |
| MDCT valve measurements | | | | | | |
| Inflow level | | | | | | |
| Dimensions, mm | 24.5, 27.0 | 21.8, 23.5 | 24.8, 25.2 | 23.3, 23.7 | 22.7, 23.3 | 23.4, 24.0 |
| Eccentricity, % | 9.3 | 7.2 | 1.6 | 1.7 | 2.6 | 2.5 |
| Expansion, % | 109.1 | 110.6 | 86.5 | 88.4 | 83.1 | 87.4 |
| Mid-stent level | | | | | | |
| Dimensions, mm | UI | 22.0, 24.3 | 25.0, 25.5 | 25.5, 25.9 | 24.5, 25.3 | 25.4, 25.5 |
| Eccentricity, % | | 9.5 | 2 | 1.5 | 3.2 | 0.4 |
| Expansion, % | | 114.2 | 95.4 | 101.5 | 92.6 | 93.8 |
| Outflow level | | | | | | |
| Dimensions, mm | 23.9, 28.4 | 22.0, 25.2 | 25.4, 27.2 | 26.2, 26.8 | 24.6, 25.7 | 25.7, 26.0 |
| Eccentricity, % | 15.8 | 12.7 | 6.6 | 2.2 | 4.9 | 1.2 |
| Expansion, % | 108.4 | 116.1 | 112.4 | 112.2 | 96 | 103.5 |
| Echocardiography | | | | | | |
| Baseline | | | | | | |
| AVA, $cm^2$ | 0.7 | 0.6 | 0.8 | 0.6 | 0.4 | 0.7 |
| MG, mm Hg | 42 | 74 | 33 | 40 | 68 | 31 |
| Post-implantation | | | | | | |
| AVA, $cm^2$ | 1.5 | 1.3 | 1.4 | 1.6 | 1.2 | 1.2 |
| MG, mm Hg | 18 | 13 | 14 | 9 | 13 | 21 |
| PAR | Mild | Mild | Trivial | Trivial | Mild | Mild |
| 1-year post-TAVR | | | | | | |
| AVA, $cm^2$ | 1.6 | 1.3 | 1.4 | 1.3 | 1.2 | 1.3 |
| MG, mm Hg | 17 | 15 | 15 | 8 | 7 | 22 |
| PAR | Mild | Mild | Trivial | Trivial | Mild | Mild |
| 2-year post-TAVR | | | | | | |
| AVA, $cm^2$ | NA | 1.4 | NA | NA | 1.2 | 1.3 |
| MG, mm Hg | | 16 | | | 8 | 22 |
| PAR | | Mild | | | Mild | Mild |
| 3-year post-TAVR | | | | | | |
| AVA, $cm^2$ | NA | 1.4 | NA | NA | NA | 1.2 |
| MG, mm Hg | | 18 | | | | 21 |
| PAR | | Mild | | | | Mild |

None of the cases had more than trivial transvalvular regurgitation. Sapien, Sapien XT, and Cribier-Edwards valves are products of Edwards Lifesciences (Irvine, California).

AVA = aortic valve area; CE = Cribier-Edwards; MDCT = multidetector computed tomography; MG = mean aortic gradient; NA = not available; PAR = paravalvular aortic regurgitation; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; THV = transcatheter heart valve; UI = uninterpretable.

(5 of 42) had a more elliptical THV than did those with trace/mild paravalvular aortic regurgitation. Our findings differ, with lower eccentricity scores and higher rates of circularity. This may be accounted for by the lower rate of moderate aortic regurgitation (1 of 50) in our study population and the absence of bicuspid valves.

Early post-implantation geometry of the self-expandable CoreValve ReValving System (Medtronic Inc., Minneapolis, Minnesota) has been demonstrated in 1 study (15) of 30 patients at an average 1.5 months after implantation. The MDCT CoreValve measurements demonstrated incomplete and nonuniform valve expansion across all stent levels. Eccentricity was greatest within the aortic annulus and the degree of frame deformation reduced with increasing distance from the aortic annulus. Noncircularity was presented in 50% (15 of 30) of CoreValve devices at the central leaflet coaptation point and 67% (20 of 30) at the nadir of the leaflets. What affect this relatively greater degree of eccentricity may have on long-term durability is not known.

**Table 6. The Effect of Oversizing THV on THV Expansion and Eccentricity**

| Valve Size Minus Annulus Diameter* (mm) | n | THV Expansion† | THV Eccentricity† |
|---|---|---|---|
| 0–2 | 22 | 102.4 ± 8.1% | 2.1 (1.2–3.2) |
| 3–5 | 28 | 99.6 ± 7.1% | 1.9 (0.9–3.0) |
| p Value | | 0.20 | 0.78 |

Values are mean ± SD or median (25th to 75th interquartile range). *Annulus measured by transesophageal echocardiography. †Expansion and eccentricity as measured at the valve inflow level.
THV = transcatheter heart valve.

**Valve type.** Our study population consisted of 3 valve types with the Sapien valve contributing the majority. The Cribier-Edwards valve and Sapien valve have the same stainless steel stent; however, they differ with the height of the fabric skirt (Sapien valve skirt is higher, covering the lower 2 cells). The Sapien XT valve consists of a cobalt chromium stent containing a more open cell design that enables a lower crimped profile (17). Radial force of both stents, however, is comparable. Although the number of Sapien XT valves analyzed is small, the eccentricity scores were low and all valves were fully expanded supporting durability of this stent.

**Study limitations.** Given the low prevalence of noncircular and underexpanded THV within our study cohort, the clinical impact of valve deformity on hemodynamics could only be assessed in a limited number of patients. It is also assumed that geometry of the deformed THV is unchanged from the time of implantation. There is selection bias because we only including patients alive at 1-year, post-TAVR follow-up, and the study cohort represents a relatively small sample of the patients that underwent TAVR at our institution. Patients with renal impairment that were excluded from MDCT may have had more calcified valves that could affect THV eccentricity and expansion. Finally, it should be clear that the purpose of our study was not to make a clinical case for routine medium-term follow-up with MDCT, but rather to use MDCT to evaluate the structural integrity and geometry of these valves.

## Conclusions

Balloon-expandable aortic valves have excellent rates of circularity with low eccentricity and maintain full expansion without stent fracture at an average 2.5 years after implantation. The impact of THV eccentricity and underexpansion on valve hemodynamic function or deterioration requires further study.

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**Key Words:** aortic stenosis ■ multidetector computed tomography ■ transcatheter aortic valve implantation ■ transcatheter aortic valve replacement.